DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6010

October 6, 1999

WARNING LETTER

CERTIFIED MAIL –
RETURN RECEIPT REQUESTED

Mr. Alexander Mogilever, President
Amros the Second, Inc.
69 Veronica Avenue
Somerset, New Jersey 08873

File No: 00-NWJ-02

Dear Mr. Mogilever:

On August 10, 11, and 25,1999, Investigators from our office visited your manufacturing facility located at 69 Veronica Avenue, Somerset, New Jersey. Physical samples and labeling for your product, "Amros Pure Natural Mixed Nuts Honey," were collected on August 10, 1999. This product, which you manufacture and distribute, is a food as defined by Section 201 of the Food, Drug, and Cosmetic Act (the Act) and is subject to regulations under Title 21 of the Code of Federal Regulations.

Your product, "Amros Pure Natural Mixed Nuts Honey," is considered misbranded under Sections 403(i)(2), 403(e)(1) and 403(q)(1) of the Act. As per Federal law, the product's labeling requires the following:

1. All product ingredients must be listed on the label. Our laboratory analyses has determined that your product contains undeclared nuts, namely peanuts, walnuts, filberts, and almonds. You are required to list out all types of mixed nuts, which may be found in your product. Further, product ingredients must be listed in descending order of predominance by weight.

2. The name and place of business of the manufacturer, packer, or distributor must be identified.

3. Appropriate nutritional information must be provided.

Since your firm only employs approximately 20 employees, you may qualify for exemption from the nutritional labeling requirements (Item #3). It is your responsibility, however, to file for exemption, on an annual basis, for each product line. To assist you, a sample Small Business Food Labeling Exemption Notice has been included with this letter.

The above violations are not meant to be an all-inclusive list of labeling violations. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes

enforced by the Food and Drug Administration. A copy of the FDA's Food Labeling Guide is enclosed for your reference.

You should take prompt action to correct the identified labeling violations and to review all product lines you manufacture and distribute to assure that they are in conformance with labeling regulations. Failure to promptly correct these violations may result in regulatory action, without further notice. These actions may include seizure of illegal products and/ or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, as to the specific steps you have taken to correct the stated violations. Please include an explanation of each step being taken to prevent the recurrence of similar violations. If corrective actions cannot be completed within 15 working days, state the reasons for the delay and the timeframe within which the corrections will be implemented.

Your reply should be sent to the Food and Drug Administration, New Jersey District Office, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054, Attn: Christine M. Marmara, Acting Compliance Officer.

Sincerely,

DOUGLAS I. ELLSWORTH
Director, New Jersey District

ATTACHMENTS:
A Food Labeling Guide
Small Business Exemption Information